3 or 4 weeks before HSCT and continued until discharge. All microbes including normal flora were specified and their susceptibility profiles to antimicrobial agents were examined. The sensitivity for the surveillance culture was defined as the rate of detecting microbes identical to pathogens of septicemia from throat or feces at least 1 week before the development of septicemia.

Results: Causative pathogens were gram-positive cocci (GPC) in 19, gram-positive rods (GPR) in 5, and gram-negative rods (GNR) in 16 episodes. The sensitivity for surveillance cultures in detecting causative pathogens of septicemia prior to the development of septicemia was 42.5% (17 of 40) in all episodes. The sensitivity was 73.7% (14 of 19) in the septicemia due to GPC, which was significantly higher than that due to GNR (18.8%; 3 of 16, $p < 0.01$).

Conclusions: We conclude that weekly surveillance culture is useful in predicting the pathogen causing septicemia, particularly in septicemia due to GPC, after allogeneic HSCT.

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HEMORRHAGIC CYSTITIS (HC) IN HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) RECIPIENTS USING ABLATIVE FLUDARABINE/BUSULFAN (FB) CONDITIONING WITH AND WITHOUT TOTAL BODY IRRADIATION (TBI)

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HC is a recognized complication of HSCT, commonly associated with the use of cyclophosphamide. Ninety one patients underwent non-cyclophosphamide, intravenous FB conditioning for HSCT (autologous [AUTO], n = 11; matched unrelated donor [MUD], n = 42; matched related donor [MRD], n = 38) at our institution from February 2005 to September 2008. The conditioning regimen consisted of fludarabine 50 mg/m^2 /day (5 days), busulfan 3.2 mg/kg/day (4 days) with or without TBI (200 cGy x 2). Urine was tested for BK virus using electron microscopy or polymerase chain reaction in most patients who developed HC. Twenty seven patients received FB with TBI (AUTO, n = 4, MUD, n = 7, MRD, n = 16) whereas 64 patients received FB without TBI (AUTO, n = 7, MUD, n = 35, MRD, n = 22). Median age was 48.6 years (range: 22–81); male: female ratio was 1.7:1. 17% patients developed HC within one year of transplantation. 6/27 (22%) of patients who received FB with TBI developed HC whereas 10/64 (16%) of those that received FB alone developed HC. All patients who developed HC had an allogeneic transplant (MUD, n = 8; MRD, n = 8). The median time to presentation was 36 days post transplant (range: 14–67). HC cases were graded as follows: grade 1(n = 4), grade 2(n = 9), grade 3(n = 2), grade 4(n = 1). BKViruria was detected in 12/16 (75%) of patients with HC. Acute graft versus host disease grade 2–4 was seen in 4/16 patients. 1/16 patient required urological intervention (bilateral ureteral stent placement), the rest were treated conservatively. There was no mortality from HC. Addition of TBI to the FB regimen did not increase the incidence of HC (p = 0.29). HC appears to be associated with allogeneic HSCT. HC was mild to moderate (grade 1–3) in most patients. The late onset of HC, in our study, suggests that the causative agent was reactivation of BKV and not direct toxicity from the conditioning regimen, which typically causes early onset HC.

Patient Characteristics and their Association with HC

	Patients (n)	HC, n (%)	P value
AUTO	11	0	
MRD	38	8 (21)	0.29
MUD	42	8 (19)	
Patient age, years			
≤48	34	5 (14)	0.047
≥48	57	11 (19)	
Conditioning Regimen			
FB	64	10 (16)	0.29
FB +TBI	27	6 (22)	

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A PILOT STUDY OF PROPHYLACTIC LIPOSOMAL AMPHOTERICIN B (AMBISOME®) FOLLOWED BY MICAFUNGIN (MYCAMINE®) FOR 100 DAYS TO PREVENT INVASIVE MOLD INFECTIONS FOLLOWING ALLOGENEIC STEM CELL TRANSPLANTATION IN PEDIATRIC RECIPIENTS

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Invasive mold infections (IMI) are a significant cause of infectious mortality post allogeneic stem cell transplant (AlloSCT). We have previously demonstrated the safety and efficacy of liposomal amphotericin B (AMB) for 100 days post AlloSCT in pediatric recipients (Roman/Cairo et al PBC, 2008). Although AMB is safe and effective for prophylaxis against IMI post AlloSCT, its associated nephrotoxicity results in its discontinuation in >10% of patients. Micafungin is a broad spectrum antifungal active against yeasts and molds with a markedly diminished side effect profile. We initiated a pilot study to determine the efficacy and safety of sequential AMB and Micafungin for antifungal prophylaxis in pediatric AlloSCT recipients. Twenty-seven patients were given AMB (3mg/kg/day) IV from d 0–45 and transitioned to Micafungin (1mg/kg/day) IV at d 45 if < grade II acute graft-versus-host-disease (GVHD), until d 100. GVHD prophylaxis was tacrolimus and mycophenolate mofetil (n = 21) for all patients as we have previously described (Osunkwo/Cairo et al BBMT, 2004) except those who received CD-34 selected PBSC (T-depleted) who received tacrolimus only (n = 6). Median age: 8 years (1–23). Gender: 9F, 18M. Diagnoses: 5-ALL, 6-AML, 2-NHL, 1-NBL, 1-HLH, 4-SAA, 1-β-Thal, 1-MAS, 4-SCD, 1-FA, 1-ALD. There were 8 CB donors (7-unrelated, 1-related), 6 UPBSC donors, 11 RBM donors and 2 URBM donors. Median follow-up is 203 days. The median switch day to Micafungin was 47. There were no reported side effects attributable to Micafungin and no one discontinued Micafungin due to toxicity. The probability of developing ≥ grade II acute GVHD and extensive chronic GVHD was 22.2% and 6.3%, respectively. The probability of IMI was zero. There were 2 documented invasive fungal infections (IFI) with Candida Parapsilosis (7.4%) and no Aspergillus IMI. One IFI occurred on AMB prior to switching to Micafungin, the other occurred 51 days after switching to Micafungin. All patients in this cohort are alive at the time of data analysis. Despite a high population of 60% unrelated donors with 25% receiving T-depleted sources, these preliminary results suggest successive antifungal prophylaxis with AMB and Micafungin is tolerable and effective in preventing IMI, especially Aspergillus, during the first 100 days post AlloSCT in pediatric recipients. Larger randomized studies are needed to compare the sequential combination of AMB/Micafungin to other standard antifungal prophylaxis regimens.

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LOW INFECTIOUS COMPLICATION RATES IN HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) RECIPIENTS: BENEFITS OF A MONTHLY MONITORING SYSTEM

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Life-threatening infections are a common cause of morbidity and mortality in HSCT recipients. We developed a prospective, real-time monitoring system for infection reporting and intervention for our inpatient HSCT unit. All positive blood, urine, sputum, skin, and stool cultures as well as *Clostridium difficile* toxin tests are reviewed monthly. We use an antibiotic algorithm specific to our HSCT patients (pts) and an on-going antibiotic restriction policy has been in place for >25 years. All infections are reviewed to assess the antimicrobial susceptibility patterns of causative infectious agents and to ensure strict compliance with the antibiotic algorithm. We performed 995 consecutive HSCT from 1994–

2006, autologous (N = 661), allogeneic (N = 254), syngeneic (N = 3), and umbilical cord blood (N = 77) HSCT. Peripheral blood (N = 849) and bone marrow (N = 69) stem cells were used as graft sources. Overall, 624 infections were identified (608 culture-positive) in 385 HSCT pts median age 46 years (male = 187, female = 198). HSCT were performed primarily for AML (N = 105) and NHL (N = 79). Documented infections were included if they occurred during an inpatient admission within 1 month (mo) prior to and 1–12 mo after HSCT. Several pts had received multiple HSCT or donor lymphocyte infusions; each was counted only if there was a documented infection during the designated time frame. Median (range) number infections/mo was 4 (1–12). During 9 separate mos in this 13 yr period, there were ≥10 infections/mo. A total of 333 bloodstream infections were identified.

Bloodstream Infections (N=333)	N (%)	GI Infections (N=113)	N (%)
Candida/other yeast	9 (3%)	Candida/other yeast	27 (24%)
Coagulase negative *Staphylococcus*	100 (30%)	*Clostridium difficile* toxin positive	75 (66%)
Escherichia coli	27 (8%)	Rotavirus antigen positive	6 (5%)
Enterobacter cloacae	12 (4%)		
Enterococcus faecalis	7 (2%)	**Genitourinary Infections (N=98)**	**N (%)**
Enterococcus faecium excluding VRE	5 (2%)	*Enterococcus* including VRE	24 (24%)
Klebsiella oxytoca	6 (2%)	*Escherichia coli*	22 (22%)
Klebsiella pneumoniae	36 (11%)	*Klebsiella pneumoniae*	9 (9%)
MRSA	3 (1%)		
Pseudomonas aeruginosa	13 (4%)	**Pulmonary Infections (N=35)**	**N (%)**
Viridans group *Streptococcus*	13 (4%)	*Aspergillus* species	4 (11%)
Staphylococcus aureus excluding MRSA	13 (4%)	Coagulase negative *Staphylococcus*	4 (11%)
VRE	23 (7%)	VRE	5 (14%)

After bloodstream infections, nosocomial gastrointestinal (GI) and genitourinary infections were most common. Infectious pneumonia was uncommon with only 35 documented infections, *Aspergillus* species was responsible for 11% (4/35). Gram positive blood stream infections predominated, most likely associated with central venous catheter use. Additionally, *C. difficile* infections remained an important cause of morbidity and mortality. Despite absence of global antibiotic prophylaxis (with the exception of Pneumocystis pneumonia prophylaxis) and not routinely performing surveillance screening before/during HSCT, we note a low infectious complication rate over the last 13 yrs. We attribute our low overall infection rate and lack of major infectious outbreaks to our system of monthly self-monitoring by our multidisciplinary team.

CRA-DATA MANAGEMENT

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IMPLEMENTATION OF CHANGE TO THE NEW PATIENT REFERRAL PROCESS

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Prior to April 2008, the process of scheduling new patient office visits with the Blood and Marrow Transplant physicians was housed within the affiliated hospital. They were responsible for taking all new referral phone calls, entering patient information into both physician and hospital management systems, and scheduling new patient appointments. Unfortunately, it became evident that there was a problem with communication and timely scheduling of patients as the clinic began receiving complaints from referring physicians. It was also confusing for patients when receiving calls from the hospital to schedule for the clinic. The clinic determined that it was necessary to take over the referral process from the hospital. Management wanted to ensure that referring physician and patient needs were being met as well as regain control over a process that directly affected the image of the clinic. It was redesigned to meet the clinic's needs:

⇒ The insurance verification reps absorbed taking the referral calls. A log was created to track referrals and call backs with a goal of returning initial calls within 24 hours.
⇒ A fax was installed at their desk to facilitate receiving medical records timely.
⇒ All patient demographics/insurance information is collected and entered into the clinic's management system. The reps began entering the information into the hospital's management system as well to simplify communication to the patient and to the hospital. This minimized the number of calls to the patient.
⇒ After verifying the patient's insurance, the appointment is scheduled. Since the process is housed in the clinic, communication has become easier with the physician coordinators thereby increasing the ability to adjust the physician's schedule in an urgent situation.
⇒ The referring physician's office is then informed of the patient's appointment assuring that the patient has been scheduled timely.
⇒ A packet is sent to the patient with an appointment reminder, maps, and necessary paperwork. Completing this ahead of time saves the patient time once in the clinic. Since making this change, the clinic has streamlined the new referral process making great improvements. Referring physicians' offices are well informed of their patient's status in being scheduled; therefore no complaints have been received since April. In addition, communication amongst clinic and hospital staff is much more efficient resulting in better customer service to new patients.

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ALLOWING GREATER USE OF INSTITUTIONAL PRACTICE MAY DECREASE COST OF CTN TRIALS

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Data management for BMT studies can be a time consuming and expensive task. Patients with complex diseases and complications can make safety vigilance and protocol adherence a challenge. When designing a trial, it is important to clearly delineate between clinical practices that must be dictated because they are vital to the integrity of the protocol versus ones that can be performed under the Clinical Practice Guidelines (CPG) of an institution. Often, when an institution is developing their own trial, they will routinely allow CPG whenever possible. Trials that are designed by cooperative groups or industry often have numerous specifications that contradict CPG resulting in a greater data management burden likely due to more time spent educating staff about differences, more intensive screening, and reporting of additional data points. To quantify the differences in data management (DM) hours we compared DM time for four CTN trials to four similar University of Michigan (UM) Investigator Initiated trials. This comparison was facilitated by the routine use of a time and effort tracker tool utilized by our center for every clinical research study. The time tracker records the amount of time spent on various trial related activities such as screening, data collection and safety reporting for every trial. CTN trials average 31.4 hours more per patient for data management than UM trials. Using the average cost for a UM data manager of $29.10 per hour, the cost differential exceeded $914 per patient. Aside from restricting the use of CPG, other factors that may add to trial cost are 1) CTN staff are remotely located and communication is therefore less efficient, 2) CTN trials require an average of 5.18 hours more to screen each